

From the INTERNATIONAL BUREAU

**PCT**

**NOTIFICATION OF TRANSMITTAL  
OF COPIES OF TRANSLATION  
OF THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**  
(PCT Rule 72.2)

To:

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KUSAMA PATENT OFFICE  
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JAPON



Date of mailing (day/month/year)  
17 February 2005 (17.02.2005)

Applicant's or agent's file reference  
TK-80

**IMPORTANT NOTIFICATION**

International application No.  
PCT/JP2003/010030

International filing date (day/month/year)  
07 August 2003 (07.08.2003)

Applicant

TEIKOKU SEIYAKU CO.,LTD. et al

**1. Transmittal of the translation to the applicant.**

The International Bureau transmits herewith a copy of the English translation made by the International Bureau of the international preliminary examination report established by the International Preliminary Examining Authority.

**2. Transmittal of the copy of the translation to the elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following elected Offices requiring such translation:

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**3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report.

**It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.**

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## PATENT COOPERATION TREATY



## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TK-80	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/JP2003/010030	International filing date (day/month/year) 07 August 2003 (07.08.2003)	Priority date (day/month/year) 09 August 2002 (09.08.2002)	
International Patent Classification (IPC) or national classification and IPC A61K 31/565, 9/70, 47/14, 47/16, 47/32, A61P 3/06, 9/10, 15/12, 19/10, 25/28, 43/00			
Applicant TEIKOKU SEIYAKU CO.,LTD.			

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of _____ sheets, as follows:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input type="checkbox"/> Box No. VI Certain documents cited</li> <li><input type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>
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Date of submission of the demand 13 February 2004 (13.02.2004)	Date of completion of this report 13 September 2004 (13.09.2004)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP2003/010030

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- This report is based on translations from the original language into the following language \_\_\_\_\_, which is language of a translation furnished for the purpose of:
- international search (under Rules 12.3 and 23.1(b))
  - publication of the international application (under Rule 12.4)
  - international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

- The international application as originally filed/furnished
- the description:  
pages \_\_\_\_\_, as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- the claims:  
pages \_\_\_\_\_, as originally filed/furnished  
pages\* \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- the drawings:  
pages \_\_\_\_\_, as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3.  The amendments have resulted in the cancellation of:

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages \_\_\_\_\_
- the claims, Nos. \_\_\_\_\_
- the drawings, sheets/figs \_\_\_\_\_
- the sequence listing (*specify*): \_\_\_\_\_
- any table(s) related to sequence listing (*specify*): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03/10030

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)

Claims 3, 4 YES

Claims 1, 2, 5 NO

Inventive step (IS)

Claims YES

Claims 1-5 NO

Industrial applicability (IA)

Claims YES

Claims 1-5 NO

**2. Citations and explanations (Rule 70.7)**

Document 1: EP, 435200, A2

Document 3: EP, 531938, A1

Document 5: WO, 00/38659, A1

Document 7: JP, 9-315957, A

Document 9: WO, 97/03698, A1

Document 11: WO, 90/06736, A1

Document 13: WO, 95/17896, A1

Document 2: EP, 421454, A2

Document 4: JP, 9-176049, A

Document 6: WO, 00/25792, A1

Document 8: JP, 2000-63267, A

Document 10: JP, 7-10759, A

Document 12: JP, 7-101864, A

**Explanation:**

Documents 1-4 cited in the ISR describe a patch for external use which has a hormone such as estradiol as the active ingredient, comprises an acrylic adhesive containing isocyanate crosslinking agent, and has a polyester film and other films, etc. Also, the blending quantity for each ingredient and the film thickness can be appropriately decided by a party skilled in the art based on the use and medicinal benefits. Therefore, the inventions described in claims 1, 2 and 5 do not appear to be novel or to be novel.

Because documents 1-13 do not describe the inventions described in claims 3 and 4, these inventions appear to be novel.

Because documents 5-13 describe a noretisteron as an active ingredient, crotamiton, oleic acid, and myristic acid isopropyl as absorption promoting agent and solvent, using these does not require any particular creativity.

Therefore, the inventions described in claims 3 and 4 do not appear to involve an inventive step.